

RFP NO. NIMH-01-DI-0001

TITLE: "Neuropsychiatric Animal Model Production & Analysis Resource

(NAMPAR)"

ISSUED BY: Robert D. Barnie

Contracting Officer

National Institute of Mental Health Contracts Management Branch

6001 Exec. Blvd., Rm. 6107, MSC 9603

Bethesda, MD 20892-8030

DATE ISSUED: December 11, 2000

PROPOSAL DUE DATE: January 16, 2001

Dear Sirs:

The National Institute of Mental Health (NIMH) invites you to submit a proposal in accordance with the requirements and instructions of Request for Proposals (RFP) No. NIMH-01-DI-0001. Proposals are being solicited under Sole Source Procedures from:

Brudnick Neuropsychiatric Research Institute (BNRI) Department of Psychiatry University of Massachusetts Medical School

in the Commerce Business Daily on October 5, 2000.

It is expected that one (1) non-competitive cost-reimbursement, completion type contract will be awarded on or before March 19, 2001 with a base period of one (1) year. **However, other sources have 45 days to respond to the synopsis that was published**

The RFP does not commit the Government to pay costs for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with any acquisition action.

SPECIAL ATTENTION SHOULD BE DIRECTED TO THE TECHNICAL PROPOSAL INSTRUCTIONS & BUSINESS PROPOSAL INSTRUCTIONS CONTAINED IN ATTACHMENT 4.

The documents included with this RFP package are as follows:

I. Streamlined RFP

- A. Statement of Work (SOW) (Attachment 1)
- B. Deliverables and Reporting Requirements (Attachment 2)
- C. Evaluation Factors for Contract Award (Attachment 3)
- II. Specific RFP Instructions and Provisions (Attachment 4)
- III. Applicable RFP References (Attachment 5)

The attachments listed above represent all the necessary information required for the submission of a proposal for this acquisition.

Your proposal must be signed by an official authorized to contractually bind your organization and must indicate that it is valid for a period of at least 120 days. One (1) original and ten (10) copies of your technical proposal and one (1) original and four (4) copies of your Business/Cost Proposal, must be received by the Contracting Officer NO LATER THAN 3:30 P.M., LOCAL PREVAILING TIME ON January 16, 2001, at one of the following addresses:

If hand-delivered or delivery service If using U.S. Postal Service

Contracting Officer
National Institute of Mental Health
Contracts Management Branch
6001 Exec. Blvd., Rm. 6107, MSC 9603
Rockville, MD 20852-9603
Contracting Officer
National Institute of Mental Health
Contracts Management Branch
6001 Exec. Blvd., Rm. 6107, MSC 9603
Bethesda, MD 20892-9603

In addition, you are reminded that the "Technical Proposal Cover Sheet" (contained in Attachment 5) must be completed in detail and used as the cover sheet for each copy of your technical proposal. New policies require submission of more detailed information than previously required. It is important that you list all professional personnel and organizations named in the proposal who will have any role in the proposed work, including: staff of the primary organization (offeror), subcontractors, collaborating organizations, and consultants. Organizational affiliation(s) must be indicated for every person named. You may use additional sheets, as needed, following the format shown in the Technical Proposal Cover Sheet. This information will be used to ensure that there will be no conflicts of interest when selecting review committee members.

Your attention is further directed to the "Proposal Intent Response Sheet" contained in Attachment 4. Please complete this form and return it to this office either via mail (to the above address), by fax or by E-mail (as indicated below) on or before January 5, 2001. This will allow us to expedite preparations for the peer review of proposals.

IF THERE ARE ANY AMENDMENTS TO THIS SOLICITATION, THEY WILL BE AVAILABE ONLY ON THE INTERNET (REFER TO THE NIMH HOME PAGE) AT: http://www.nimh.nih.gov/grants/indexcon.cfm

Questions concerning any areas of uncertainty, which in your opinion, require clarification or correction, must be furnished in writing (Fax or e-mail is also acceptable) to Robert D. Barnie, and marked "Offeror's Questions, RFP No. NIMH-01-DI-0001". If you have any additional questions regarding this RFP, please contact me by e-mail at Rb245s@.nih.gov, by telephone at (301) 443-2696 or by Fax at (301) 443-0501. Collect calls will not be accepted.

ANY DISCUSSION OF THIS RFP WITH ANY INDIVIDUAL(S) OUTSIDE THE CONTRACTS MANAGEMENT BRANCH, NIMH, MAY RESULT IN DISQUALIFICATION OF THE OFFEROR AND REJECTION OF ANY PROPOSAL SUBMITTED.

Sincerely,

/s/

Robert D. Barnie, Contracting Officer Contracts Management Branch, ORM National Institute of Mental Health, NIH

Attachments: 1-5

ATTACHMENT 1 to STREAMLINED RFP No. NIMH-01-DI-0001

ATTACHMENT V to STREAMLINED RFP No. NIMH-01-DI-0001

Statement of Work

Title: "Neuropsychiatric Animal Model Production & Analysis Resource (NAMPAR) Training Program"

I. Contract Objectives

A. Objectives

The contractor will establish and maintain a Neuropsychiatric Animal Model Production and Analysis Resource (NAMPAR) Training Program that will provide an integrated and comprehensive training, consultation, production and evaluation resource for NIMH/NIH funded investigators. The contractor will provide for the accessibility, maintenance, and updating of the NAMPAR, and for the development of appropriate additional testing paradigms, in a manner that will facilitate the replication of the facility by trainees.

II. Services to be Performed

A. General Requirements shall:

- 1. Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary labor, materials, supplies, equipment and services to accomplish the work of this contract.
- 2. This contract requires the contractor to provide services in accordance with the below specific requirements in order to fulfill contract objectives. All work done under this contract shall be under the general guidance and technical monitoring of the NIMH Government Project Officer (GPO). Contact between the GPO and the Contractor shall include frequent phone and e-mail contacts, faxing of information, and periodic meetings.

B. Specific Requirements

TASK 1.

The contractor shall assemble and maintain a Neuropsychiatric Animal Model Production and Analysis Resource (NAMPAR) Training Program for the production and analysis of animal models of neuropsychiatric disorders and as a site for scientific meetings on topics related to the mission of the resource. Specifically, the contractor shall:

- 1. Enable access to qualified biologists and geneticists and provide training and assistance in the evaluation of project planning, directions and data analysis;
- Provide training in and enable transgenic and embryonic stem cell procedures, including planning and assembly of DNA constructs, performance of injection and harvesting and reimplantation surgical procedures, setup and maintenance of mouse pedigree tracking, and appropriate selection and performance of model specific behavioral analysis procedures;
- 3. Provide, develop and maintenance animal models, appropriate MRI (awake animal imaging), behavioral testing, and construct-specific DNA analyses, that are designed to train NIMH staff and grantees;
- 4. Provide complex and specialized procedures such as tissue harvesting and preservation (in fixative or frozen), cell line establishment and immortalization, and dissemination of samples in accordance with NIH guidelines, and in a manner that is designed to train NIH staff and grantees;
- 5. Assure that NAMPAR training and services are made available to NIMH staff and grantees at no cost and charge a fee for service to non-NIH requestors, the fee depending on the amount of consumables and types of services utilized;
- 6. Facilitate any copyrights and/or patents in accordance with NIH guidelines;
- 7. Provide updates and training on procedures in construct preparation, MRI imaging and behavioral phenotypic paradigms;
- 8. Provide a front-end resource that can become partially or fully user supported; and
- 9. Ensure that the resource program and facilities will comply with OSHA standards. The contractor's animal facilities must be AAALAC accredited. All procedures performed under the NAMPAR will be in accordance with all federal, state and local regulations, policies and guidelines.

TASK 2. The Contractor shall submit the following reports to the GPO and the Contracting Officer (CO).

- 1. Monthly Progress Reports. The Contractor shall submit three (3) copies of a brief letter-type progress report. The report shall detail: (1) activities undertaken; (2) problems, if any, encountered and how they were (or will be) resolved; (3) planned activities for the upcoming reporting period; (4) any anticipated problems and plans for there resolution; and (5) a statement that the contract will (or will not) be completed in accordance with the planned schedule and will (or will not) be completed within the budgeted amount. If the contract will not be completed in accordance with the planned schedule or within budget provide an explanation and details of what actions will be taken to bring the contract back on schedule and/or within budget.
- 2. Final Report: The Contractor shall submit three (3) copies of the final report to the GPO on or prior to the expiration date of the contract. In addition, one (1) copy of the final report shall be furnished to the CO. This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved.

ATTACHMENT 2 to STREAMLINED RFP No. NIMH-01-DI-0001

DELIVERABLES AND REPORTING REQUIREMENTS

1. DELIVERIES OR PERFORMANCE

Performance of this contract shall begin on the effective date and shall not extend beyond the estimated completion date of the contract unless the period is extended by modification to the contract.

2. DELIVERY SCHEDULE

A. After the contract award date, the Contractor shall deliver the following items/reports to the GPO in accordance with the delivery schedule set forth below:

ITEM/DESCRIPTION	QUANTITY	DUE DATE
1. Monthly Progress Report	3	15 days after the close of each reporting
		period
2. Final Report	3	By contract expiration date
3. Other Materials	3	As required by the GPO

- B. The items/reports identified shall be addressed and delivered to the GPO in the quantities stated. An electronic copy of the Final Report shall also be submitted to the GPO. In addition, one (1) copy of each Monthly Progress Report and one (1) copy of the Final Report shall be delivered to the Contracting Officer by the specified delivery date.
- C. The following FAR Clauses applies to this contract and are incorporated by reference with the same force and effect as is set forth in the full text.

FAR CLAUSE	TITLE AND DATE
52.242.15	Stop Work Order (August 1989), Alternate I (April 1984)
52.246-8	Inspection of Research and Development – Cost Reimbursement (April 1984)

ATTACHMENT 3 to STREAMLINED RFP No. NIMH-01-DI-0001

EVALUATION FACTORS FOR CONTRACT AWARD

1. GENERAL

The technical proposal will receive paramount consideration in the selection of the Contractor(s) for this acquisition. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. However, cost/price may become a critical factor in source selection in the event that two or more offerors are determined to be essentially equal following the evaluation of all factors other than cost or price. In any event, the Government reserves the right to make an award(s) to that offeror(s) whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. TECHNICAL EVALUATION CRITERIA

Proposals submitted in response to this RFP will be evaluated based on the following factors, which are listed and weighted in order of their relative importance. Proposals will be judged solely on the written material provided by the Offeror.

The evaluation factors and assigned weights which will be used in the technical review of proposals are:

Evaluation Criteria Weights

1. Technical Approach

The technical approach should include the adequacy of the technical approach and methodology to achieve the project

the technical approach should include the adequacy of the technical approach and methodology to achieve the project objectives, including a discussion of potential problems and proposed solutions.

2. Personnel 30

Demonstrated qualifications, availability, and experience of professional and technical personnel to perform the tasks of this contract as demonstrated by resumes and discussion.

3. Understanding the Problem

Offeror must: 1) demonstrate a thorough understanding of the objectives of this project by documenting that one or more key staff have experience with projects of similar complexity and have experience with the full cycle of planning, setting-up, monitoring, and evaluating an animal model. Scientific publications or abstracts are sufficient; 2) have direct knowledge and hands on expertise in planning, setup, production and analyses that are necessary to setup, maintain and enhance a state-of-the-art neuropsychiatric animal model production and analysis resource; and 3) demonstrate the capacity to assist the research field.

4. Management Capability

The offeror must show: 1) management and organizational skills and plans that will provide assurance that the project milestones and goals will be met effectively and in a timely manner; 2) demonstrated capacity to meet the needs of the research field in terms of quality and timeliness and to work with researchers to maximize the usefulness of the resource. Such management capability can be demonstrated by documenting that one or more key staff members have experience with projects of similar complexity, and that milestones were appropriately set and goals were met.

5. Facilities and Equipment

The offeror shall describe the availability and proposed utilization of appropriate facilities and equipment required to successfully perform the work requirements.

25

10

5

8

ATTACHMENT 4 TO STREAMLINED RFP No. NIMH-01-DI-0001

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

A. JUST IN TIME

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the discussion process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of <u>cost/pricing information</u> will only be required to be submitted from the apparent successful offeror(s). The special procedures for submission of this documentation are set forth below:

Travel Policy, Annual Report, Total Compensation Plan and Subcontracting Plan: Only the apparent successful offeror will be required to submit these documents as part of their Final Proposal Revision (FPR).

Cost Pricing Information: The offeror's business proposal shall include the basic cost/pricing information specified in Paragraph N , "Business Proposal Instructions" subparagraph 2, "Cost and Pricing Data" of this RFP. In addition, the government may require apparent successful offerors to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested during negotiations, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. (The information may also include submission and certification of cost or pricing data.)

B. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications, specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

- 1. The North American Industry Classification System (NAICS) code for this acquisition is <u>541380</u>.
- 2. The small business size standard is \$5 Million.

THIS REQUIREMENT IS <u>NOT</u> SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every

solicitation (except for foreign acquisitions), the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

C. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that one award will be made from this solicitation and that the award will be made on/about March 19, 2001.

It is anticipated that the award from this solicitation will be a one-year, Cost Reimbursement, Completion type contract.

D. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer (CO) is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

E. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the CO cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

F. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

G. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in Attachment 3 of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

H. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

I. SERVICE OF PROTEST (AUGUST 1996) – FAR 52.233-2

Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the CO (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

If hand-delivered or delivery service If using U.S. Postal Service

National Institute of Mental Health
Contracts Management Branch
Attn: Contracting Officer
6001 Executive Boulevard
Room 6107, MSC 9603
Rockville, Maryland 20852

National Institute of Mental Health
Contracts Management Branch
Attn: Contracting Officer
6001 Executive Boulevard,
Room 6107, MSC 9603
Bethesda, Maryland 20892-9603

The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

J. SAFETY AND HEALTH (DEVIATION) PHS 352.223-70 (Aug 1997)

- (a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).
- (b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer in conjunction with the project or other appropriate officer, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause set forth in this contract.
- (c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement

agency and the time frame allowed by the agency to accomplish the necessary corrective action.

- (d) If the Contractor fails or refuses to comply promptly with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.
- (e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)

K. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1140 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone 301-435-1986). In addition, one copy of the annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer at the address listed below. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted within 90 days after contract expiration to the following address:

Robert D. Barnie Contracting Officer National Institute of Mental Health Contracts Management Branch 6001 Executive Blvd., Rm. 6107 (MSC 9603) Rockville, Maryland 20892-9603

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison" an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH.

2. INSTRUCTIONS TO OFFERORS

L. GENERAL INSTRUCTIONS

The following instructions will establish the acceptable minimum requirements for the format and content of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions. Also, please note that the technical proposal must be organized and presented in accordance with the "Technical Proposal Instructions" (Paragraph M. below).

(1) **Type Contract and General Clauses**

It is contemplated that a cost-reimbursement/completion type contract will be awarded. (See General Information). Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the address in the attached solicitation cover letter, and mark each package as follows: RFP No. NIMH-01-DI-0001 TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

(a) COVER PAGE

Include RFP number, title, name of organization, name of Principal Investigator, names of other offeror key personnel, name of any subcontractor(s) and their proposed Principal Investigator(s), names of any collaborators or consultants, and indicate whether the proposal is an original or a copy.

(b) TECHNICAL PROPOSAL

Format and organization of the technical proposal must follow the Table of Contents, and must include the information requested in the Technical Proposal Instructions and as otherwise specified in the APPLICABLE RFP REFERENCES (ATTACHMENT 5).

(c) BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as otherwise specified in the APPLICABLE RFP REFERENCES (ATTACHMENT 5).

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Attachment 5).

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resource information, such as labor-hours and categories, materials, subcontracts, travel, etc, and associated cost so that the offeror's understanding of the project may be evaluated. (See Attachment 5). However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) Confidentiality of Proposals (HHSAR 352.215-12, Restriction on Disclosure and Use of Data (April 1984))

The proposal submitted in response to this RFP may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required

to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) Officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act, and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal; the Government shall have the right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act.

The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

In addition, the offeror should mark each page of data it wishes to restrict with the following legend:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal."

NOTE: Offerors are cautioned that proposals submitted with the restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(7) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Attachment 3, "Evaluation Factors for Contract Award".

(8) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the CO determines that the initial prices are fair and reasonable and that discussions are not necessary.

(9) Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon(as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(10) Care of Live Vertebrate Animals

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects – (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office for the Protection from Research Risks (OPRR), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act,

and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OPRR. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OPRR, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OPRR, OLAW may be contacted by Rockledge Center I – Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, ext. 234. FAX copies of the PHS Policy are available at (301)402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

(11) **Selection of Offerors**

- a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-
 - All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct limited negotiations after Final Proposal Revisions (FPRs) in accordance with HHSAR 315.670.
- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost

factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIMH reserves the right to make a single award, multiple awards, or no award at all from this RFP. In addition, the RFP may be amended or canceled as necessary to meet NIMH requirements. Synopses of awards exceeding \$25,000 will be published in the Commerce Business Daily.

(12) Small Business Subcontracting Plan

**** This document is INCLUDED in the "Just In Time" procedures.

If the proposed contract exceeds a total estimated cost of \$500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation.

- a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c) The offeror understands that:
 - (1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
 - (2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.
 - (3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and

- with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
- (4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
- (5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.
- (6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d) Each plan must contain the following:
 - (1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, women-owned, and HUBZone small business concerns as subcontractors.
 - (2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, and HUBZone Small Businesses.
 - (3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, women-owned, and/or HUBZone small business concerns.
 - (4) A description of the method used to develop the subcontracting goals.
 - (5) A description of the method used to identify potential sources for solicitation purposes.

- (6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged, women-owned, and HUBZone small business concerns.
- (7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
- (8) A description of the efforts the offeror will make to assure that small, small disadvantaged, women-owned, and HUBZone small business concerns have an equitable chance to compete for subcontracts.
- (9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$500,000 adopt a plan similar to the plan agreed upon by the offeror.
- (10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.
- (11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, women-owned, and HUBZone small business concerns and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan and Attachment 5 to the RFP.

(13) Salary Rate Limitation in Fiscal Year 2000

Offerors are advised that pursuant to P.L. 106-113, no NIH Fiscal Year 2000 (October 1, 1999 - September 30, 2000) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses). This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The salary rate limitation set by P.L. 106-113 applies only

to Fiscal Year 2000 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level II* annual salary rate limit also applies to individuals proposed under subcontracts. P.L. 106-113 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level II."

*This rate may change periodically. For your information, the rate can be found at URL:

http://www.opm.gov/oca/2000tbls/Execses/html/execschd.htm

Note: The Salary Rate Limitation Clause will be updated in the contract to reflect information pertaining to Fiscal Year 2001.

(14) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

- (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
- (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose

financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

- (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and(2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- (g) Certify, in each application/proposal for funding to which the regulations applies, that:
 - (1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
 - (2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
 - (3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and
 - (4) the Institution will otherwise comply with the regulations.

(15) Institutional Management of Conflicting Interests

(a) The designated official(s) must: (i) review all financial disclosures; and(ii) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

- i. public disclosure of significant financial interests;
- ii. monitoring of research by independent reviewers;
- iii. modification of the research plan;
- iv. disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
- v . divestiture of significant financial interests; or
- vi. severance of relationships that create actual or potential conflicts of interests.
- (b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (1) of this section, as the Institution deems appropriate.

(16) **ROTC** Access and Federal Military Recruiting on Campus

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (i) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (ii) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(17) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates the following solicitation provisions by reference with the same force and effect as if they were given in full text. Upon request, the CO will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
- b. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
- c. Order of Precedence Uniform Contract Format, FAR Clause 52.215-8 (October 1997)
- d. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000) FAR Clause 52.222-24, (February 1999)
- e. Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data, FAR 52.215-20 (October 1997)

M. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted for each proposed objective indicating how each aspect of the objective is to be accomplished. Your technical proposal should be in as much detail as you consider necessary to fully explain your proposed technical approach and methodology. The technical proposal should reflect a clear understanding of the nature of the work being undertaken and must include information on how the project is to be organized, staffed, and managed. The Technical Proposal should be organized and presented as stated below.

1. Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a. **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your

proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the Statement of Work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the CO. Unless the RFP indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b. **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED

THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible. If the Principal Investigator proposed for this RFP is committed in excess of 100% of his/her time the proposal must include appropriate explanations.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- -The specific items or expertise they will provide.
- -Their availability to the project and the amount of time anticipated.
- -Willingness to act as a consultant.
- -How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications. Resumes must not exceed two pages.

c. Facilities and Resources

List/describe all facilities and resources available for this project, including any equipment.

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause:

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into and between the twentieth and twenty-first centuries and Year 1999 and Year 2000 and leap year calculations.

d. Summary of Related Activities

The offeror shall complete and include with the technical proposal the "Summary of Current and Proposed Activities" form, see Attachment 5, of this RFP. Include this form with the Other Considerations portion of your technical proposal.

2. **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Evaluation Factors for Contract Award (Attachment 3).

3. Additional Technical Proposal Information

- a. Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b. The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by the initial review panel. This evaluation

produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

4. Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- (a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the Statement of Work will be accomplished within this working relationship.
- (b) Unique arrangements which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- (c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- (d) Other factors you feel are important and support your proposed research.
- (e) Recommendations for changing reporting requirements or other deliverables if such changes would be more compatible with the offeror's proposed schedules.

N. BUSINESS PROPOSAL INSTRUCTIONS

1. **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. Cost and Pricing Data

- (a) General Instructions
 - (1) You must provide the following information on the first page of your pricing proposal:
 - (i) Solicitation, contract, and/or modification number;
 - (ii) Name and address of offeror, to include DUNS number;
 - (iii) Name and telephone number of point of contact;
 - (iv) Name of contract administration office (if available):

- (v) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other):
- (vi) Proposed cost; profit or fee; and total;
- (vii) Whether you will require the use of Government property in the performance of the contract, and, if so, what property; (viii) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
- (ix) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR15.4035(b)(1) and Table 152. By submitting this proposal, we grant the CO and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
- (x) Date of submission; and
- (xi) Name, title and signature of authorized representative.
- (b) In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.
- (c) As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including

- (1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
- (2) The nature and amount of any contingencies included in the proposed price.
- (d) You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed research objective, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" (see paragraph 3 below). You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
- (e) When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
- (f) Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
- (g) If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
- (h) As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

3. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

(a) Direct Labor

Provide a time-phased (e.g. monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish basis for estimates.

(b) Fringe Benefits

Show fringe benefits as a separate line item. Include the rates(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or organizational guidelines.

(c) Materials and services

Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.4034. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2, below. These requirements also apply to all subcontractors if required to submit cost or pricing data.

- (1) Adequate Price Competition. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.4034 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR31.20526(e)).
- (2) All Other. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.4034 and not otherwise exempt, in accordance with FAR 15.4031(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The CO may require you to submit

cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

(d) Indirect Costs

Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

(e) Special Equipment

If direct charge, list any equipment proposed including description, price, quantify, total price, purchase of lease, and the basis for pricing.

(f) Travel

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

(g) Other Costs

List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

(h) Royalties

If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:

- (1) Name and address of licensor.
- (2) Date of license agreement.
- (3) Patent numbers.
- (4) Patent application serial numbers, or other basis on which the royalty is payable.
- (5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
- (6) Percentage or dollar rate of royalty per unit.
- (7) Unit price of contract item.
- (8) Number of units.
- (9) Total dollar amount of royalties.
- (10) If specifically requested by the CO, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.20537).
- (i) Facilities Capital Cost of Money (Commercial Organizations, only)

When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASBCMF and show the calculation of the proposed amount (see FAR 31.20510).

4. Formats for Submission of Line Item Summaries

A separate cost/price estimate shall be provided for each research objective that you may propose. Individual cost/price estimates shall be furnished in accordance with the detailed breakdown in the format similar to that shown on the "Business Proposal Cost Information" form, see Attachment 5 of this RFP. For each separate cost/price estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. Further, in an effort to assist the cost proposal review process, Offerors who have prepared their business proposal using the following software spreadsheet(s) on a computer disk (high density) along with the submission of your paper copies of the business proposal. IBM PC compatible software programs are: Excel; Lotus 1-2-3; and Quattro Pro.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at URL: http://rcb.nci.nih.gov/forms/cpi.htm

5. There is a clear distinction between submitting cost or pricing data and merely

making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the CO or an authorized representative. As later information comes into your possession, it should be submitted promptly to the CO in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

6. By submitting your proposal, you grant the CO or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price. [Note to Offerors of RFPs using "JUST IN TIME" procedures: Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.

7. Total Compensation Plan - Instructions

**** This document is INCLUDED in the "Just In Time" procedures. ****

- a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors INCLUDED IN DISCUSSIONS WILL BE REQUIRED TO SUBMIT a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
- b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

8. Total Compensation Plan - Evaluation

a) Total Compensation Plan (Professional Employees)

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) Cost (Professional Compensation)

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) Other (Labor Relations)

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) Federal Acquisition Regulation Clauses incorporated by Reference

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

9. **Qualifications of the Offeror**

a) You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

(1) General Experience

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

(2) Organizational Experience Related to the RFP

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(3) **Performance History**

<u>Performance history</u> is defined as meeting contract objectives within <u>delivery</u> and <u>cost schedules</u> on efforts, either past or ongoing, which is comparable or related to the effort required by this RFP.

(4) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

(5) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and, while not a specific weighted evaluation factor, they are inherent in one or more technical evaluation criterion. Also, they may be used to conduct a relative assessment of offerors during the source selection process if the evaluation factors for contract award, in the specific RFP so indicate.

10. Property, Equipment, Facilities

- (a) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the CO. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes, in addition to the description and estimated cost of each item:
 - (1) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
 - (2) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
- (b) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
- (c) If an offeror intends to use existing Government-owned facilities in the performance of this proposed contract, the following shall be furnished with the offer: (1) Description and value of all Government production and research property which the offeror or his/her anticipated subcontractors propose to use on a rent-free basis and the cognizant Government Contract Number; (2) Written permission of the CO having cognizance of the property for use of that property without charges; (3)

Amount of use (in months) to be made of such property, and (4) Amount of rent which would otherwise be charged for such use, computed in accordance with applicable procurement regulations.

(d) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

11. Royalties

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

12. Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

- (1) The solicitation number (or other procurement identification number).
- (2) The offeror's name and remittance address, as stated in the offer.
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
- (4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
- (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

13. Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

14. Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- (a) Willingness to perform as a subcontractor for specific duties (list duties).
- (b) What priority the work will be given and how it will relate to other work.
- (c) The amount of time and facilities available to this project.
- (d) Information on their cognizant field audit offices.
- (e) How rights to publications and patents are to be handled.
- (f) A complete cost proposal in the same format as the offeror's cost proposal.

15. Representations and Certifications

One copy of the Representations and Certifications shall be completed and signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor. (See Attachment 5 of this RFP.)

PROPOSAL INTENT RESPONSE SHEET - PROPOSAL INTENT RFP NIMH-01-DI-0001

PLEASE REVIEW THE ATTACHED RFP. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE ON OR BEFORE **January 5**, **2001.** YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION. CHECK ONLY ONE BOX.

DO INTEND TO SUBMIT A PROPOSAL			
DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:			
PED NAME AND TITLE:			
ΓΙΤUTION:			
NATURE:			
EPHONE NO.:			
AIL ADDRESS:			
X NO			
ΓΕ:			
LABORATORS/CONSULTANTS - Provide name(s) and institution(s): (Continue on additional pages if necessary)			

TO: National Institute of Mental Health Contracts Management Branch Attn: Robert D. Barnie 6001 Exec. Blvd., Rm. 6107, MSC 9603 Bethesda, MD 20892-9603 FAX (301) 443-0501 Rb245s@nih.gov

ATTACHMENT 5 TO STREAMLINED RFP No. NIMH-01-DI-0001

APPLICABLE RFP REFERENCES

- A. The following general clauses and provisions are applicable to this specific RFP depending on your organizational status: Negotiated Cost-Reimbursement Contract with an Educational Institution, Negotiated Cost-Reimbursement Contract with a Non-Profit or, Negotiated Cost-Reimbursement Research and Development Contract. The clauses are located in the file General Clauses at URL: http://rcb.nci.nih.gov/clauses/clauses.html.
- B. The following items are applicable to this specific RFP and are located in the file entitled (except as noted) <u>FORMS</u>, <u>FORMATS AND ATTACHMENTS</u> at URL: http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm

SUBMIT WITH TECHNICAL PROPOSAL (with original and every copy of technical proposal)

- 1. Technical Proposal Cover Sheet
- 2. Summary of Current and Proposed Activities
- 3. Technical Proposal Cost Information

SUBMIT WITH BUSINESS PROPOSAL:

- 1. Proposal Summary and Data record, NIH-2043, with every copy of business proposal.
- 2. Business Proposal Cost Information
- **3.** Disclosure of Lobbying Activities, OMB SF-LLL, only one completed and signed original
- Representations and Certifications Negotiated Contract, only one completed and signed copy. Use copy available at URL: http://rcb.nci.nih.gov/forms/rcneg.pdf If unable to access this copy inform the Contracting Officer so that a copy can be mailed to your attention.

OTHER - TO BE SUBMITTED LATER:

- 1. Certificate of Current Cost or Pricing Data, NIH-1397, to be submitted with FPR, if required by the CO
- 2. DHHS Small, Small Disadvantaged, HUBZone and Women-Owned Small Business Subcontracting Plan, to be submitted as directed by the CO

ANTICIPATED TO BE INCLUDED AS CONTRACT ATTACHMENTS:

- 1. Invoice Instructions for Cost-Reimbursement Type Contracts, NIH(RC)-1
- 2. NIH 2706, Financial Report of Individual Project/Contract, the form with instructions

3. Procurement of Certain Equipment, NIH(RC)-7

C. The Sample Contract Format for R&D Cost Reimbursement contracts is located in the file entitled, FORMS, FORMATS AND ATTACHMENTSS at URL: http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm. Supplemental information pertaining to Section G of the Sample Contract Format include the following:

Section G, "Contract Administration Data" paragraph entitled "Invoice Submission" is amended to read as follows:

Invoice Submissions/Contract Financing Request

Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9. Invoice/financing requests shall be submitted as follows:

a. An original and two copies to the following designated billing office:

If hand-delivered or delivery	y Service	If using U.S. Postal Service
-		

Contracting Officer
Contracts Management Branch, ORM
National Institute of Mental Health
National Institute of Mental Health
6001 Executive Boulevard
Room 6107, MSC 9603
Rockville, Maryland 20852
Contracting Officer
Contracts Management Branch, ORM
National Institute of Mental Health
6001 Executive Boulevard
Room 6107, MSC 9603
Rockville, Maryland 20852
Bethesda, Maryland 20892-9603

Inquiries regarding payment of invoices should be directed to the designated billing office (301) 443-2696.

- b. At a minimum, the Contractor agrees to include the following information on each invoice:
 - 1. Contractor's name and invoice date,
 - 2. NIMH's Contract number, or other authorization for delivery of property and/or services
 - 3. Description, cost or price, and quantity of property and/or services actually delivered or rendered.
 - 4. Shipping and payment terms,
 - 5. Other substantiating documentation or information as required by the contract (see paragraph G.3.c, "NIMH Supplemental Billing Instructions" below,
 - 6. Name where practicable, title, phone number, and complete mailing address of responsible official to whom payment is to be sent.

c. NIMH Supplemental Billing Instructions

- 1. The contractor agrees to provide, as applicable, a detailed breakdown on each invoice of the following cost categories:
 - (a) Direct Labor List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.
 - (b) Fringe Benefits Cite rate and amount
 - (c) Overhead Cite rate and amount
 - (d) Materials & Supplies Include detailed breakdown.
 - (e) Travel Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate.
 - (f) Consultant Fees Identify individuals and amounts.
 - (g) Subcontracts Attach subcontractor invoice(s). (Should be in same format and detail as required of the Prime Contractor.) Include COA Letter Number if applicable.
 - (h) Equipment Cite authorization and amount.
 - (i) G&A Cite rate and amount.
 - (i) Total Cost
 - (k) Fee (if applicable)
 - (l) Total Cost & Fee

Monthly invoices must include the cumulative total expended to date, adjusted (as applicable) to show any amounts suspended or disallowed by the Government.

2. The contractor agrees to immediately notify the contracting officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Funds and Limitation of Cost Clauses in the contract.

Section G. "Contract Administration Data" the paragraph entitled "POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE" is amended to add:

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://ocm.od.nih.gov/cdmp/cps contractor.htm

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an

alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

The offerors attention is also called to Section H, "Special Contract Requirements" the paragraph entitled "Animal Welfare Assurance" — Any contractor receiving an award resulting from this solicitation must be in compliance with this clause which reads as follows:

Animal Welfare Assurance

The Contractor shall obtain, prior to the start of any work under this contract, an approved Animal Welfare Assurance from the Office of Protection from Research Risks (OPRR), Office of Laboratory Animal Welfare (OLAW), Office of the Director, NIH, as required by Section 1-43-30 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The Contractor shall maintain such assurance for the duration of this contract, and any subcontractors performing work under this contract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance.